

### REMARKS/ARGUMENTS

Applicant had previously elected to prosecute Claims 19-25 and, concurrently with such election, added new Claims 26 and 27. The Examiner has acknowledged that Claim 19 is generic to the species recited in dependent Claims 26 and 27. This is Applicant's understanding and intention that, if Claim 19 is deemed allowable, then dependent Claim 26 will be automatically reinstated. If this understanding and intention differs from the Examiner's understanding or intention, it is requested that the Examiner telephone Applicant's undersigned counsel to discuss the prior election of species and the appropriate procedure regarding dependent Claims 26 and 27.

In the Office Action, Claims 19-25 and 27 were rejected under 35 U.S.C. § 103 as being unpatentable over the combination of United States Patent No. 5,531,776 (Ward et al.) and published United States Patent Application No. 2001/0041923 (Dobak, III).

Applicant notes that the "Background of the Invention" section of Ward et al. includes a broad discussion of numerous maladies and treatment modalities including; cardiac arrest, various types of cardiopulmonary resuscitation (CPR), cardiopulmonary bypass, cardiogenic shock, head injury, hypothermia, pneumatic anti-shock garments, intra-aortic balloon pumping, thoracotomy and cross-clamping of the aorta. Although Ward et al.'s background section does discuss intraaortic balloon pumping and hypothermia as separate prior art modalities for treating certain conditions or maladies, Applicant does not see that Ward et al.'s "Background of the Invention" section describes the concurrent administration of hypothermia and intra-aortic balloon pumping. Furthermore, as the Examiner has correctly noted, Ward et al. contains no disclosure or suggestion of the use of any endovascular heat exchange device to effect cooling by exchanging heat with the blood.

Ward et al.'s "Description of the Preferred Embodiment" section does include descriptions of three (3) embodiments of a device that is inserted into a patient's esophagus, *not* into a patient's blood vessel. One embodiment is an "apparatus 20" which is inserted into the esophagus and includes an "expandable portion 24" which can be used to displace the wall of the esophagus in the

direction of the descending thoracic aorta, thereby continuously or intermittently constricting the aorta. At col. 12, line 56-col. 13, line 13, Ward et al. describes intermittent use of a displacement mechanism 26 to cause the esophagus wall to intermittently compress the aorta in synchrony with the cardiac cycle, "this simulating intra-aortic balloon pumping. (col. 12, lines 60-61, emphasis added) However, it must be recognized that such "simulated" intra-aortic balloon pumping by trans-esophageal compression and decompression of the aortic wall does not constitute actual intra-aortic balloon pumping.

Ward et al. also describes another embodiment which comprises an "apparatus 60" which is inserted into the esophagus of the patient and includes a "heat transfer surface 60" which can warm or cool blood flowing through the aorta only by either delivering heat *through* the wall of the esophagus and *through* the wall of the aorta or withdrawing heat *through* the wall of the esophagus and *through* the wall of the aorta. Thus, Ward et al.'s technique for trans-esophageal warming or cooling blood is procedurally and functionally quite different from applicant's technique wherein an endovascular heat exchanger is used to exchange heat directly with the flowing blood.

Ward et al. also describes an other embodiment that is an "apparatus 80" which is useable to effect the trans-esophageal transfer of heat into or out of the blood as well as for effecting "substantially complete" occlusion of the descending aorta. At col. 15, lines 49-65 Ward et al. does state that this embodiment of the "apparatus 80" can also be used to *simulate* intra-aortic balloon pumping by intermittent displacement of the esophageal wall such that it compresses the aorta.

Also, Ward et al. does not describe or suggest the placement of any temperature sensor in the patient's body or the use of any controller to receive information relating to the patient's body temperature and to control the amount or direction of trans-esophageal heat transfer in response to any sensed or measured body temperature.

Dobak describes heat exchange catheters that are insertable into a blood vessel to warm or cool blood flowing through the blood vessel. However, Dobak does not make any mention of intra-

aortic balloon counterpulsation, intra-aortic balloon pumping or any method or device that simulates or produces an effect similar to intra-aortic balloon pumping. Although Dobak's does, at Paragraph # 43, mention that an esophageal temperature probe had been used to generate experimental data from sheep indicated by curve 82 in Figure 10, Dobak does not describe or suggest the placement of any body temperature measuring apparatus in patients concurrently with the use of his endovascular heat exchange catheter. Furthermore, Dobak does not describe the use of any controller to receive information relating to the patient's body temperature and to control the amount or direction of trans-esophageal heat transfer in response to any sensed or measured body temperature. Rather, Dobak purports to be able to determine the time required to reach a target temperature solely on the basis of the rate of heat or power loss. (See, for example, Paragraph # 43) Thus, Dobak does not describe or suggest the use a any temperature sensor for monitoring the patient's body temperature in combination with a controller that controls the rate or direction of heat exchange in response to feedback from a body temperature sensor.

As presently amended, independent Claim 19 recites that the heat exchange catheter system provided in Sep A includes a temperature sensor for sensing the temperature of at least a portion of the patient's body as well as a controller adapted to receive an indication of the sensed patient temperature from the temperature sensor and to control the heat exchanger in response to said sensed patient temperature such that the heat exchanger will cool at least a portion of the patient's body to a target temperature that is at least 1 °C below normothermia. Also, Step F of Claim 19 requires that the heat exchange catheter system be used concurrently cool at least a portion of the patient's body to a target temperature that is at least 1 °C below normothermia concurrently with intra-aortic balloon counterpulsation. Applicant respectfully submits that the combination of steps recited in independent Claim 19 is not obvious over the combination of Ward et al. and Dobak, or any other prior art of record.

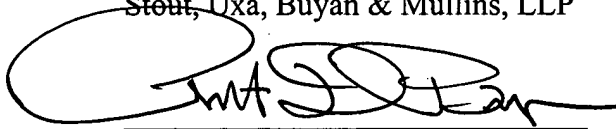
On the basis of the foregoing, independent Claim 19 is believed to be in condition for allowance. Dependent Claims 20-27 further limit or add to the subject matter of Claim 19 and are this believed to be in condition for allowance as well. Claim 19, as currently amended, remains

generic to the species of both Claims 26 and 27. Thus, reinstatement of Claim 26 is believed to be in order.

Reexamination and issuance of a Notice of Allowance with respect to Claims 19-27 is earnestly solicited. The Examiner is invited to telephone Applicant's counsel to discuss any perceived reasons why a Notice of Allowance should not issue at this time.

Respectfully submitted,  
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Dated: August 21, 2003

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